Regulatory Peer Review

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Introduction

The diverse processes of peer review are familiar within the scientific community, where they serve a critical role in the allocation of such scarce resources as research funds and journal space, as well as in helping to produce reliable knowledge (Chubin and Hackett 1990). In part because of the perceived success of peer review for funding and publication, reformers have sought to incorporate peer review into the policy making arena in efforts to improve the use of scientific knowledge, reduce the occurrence of legal challenges, and achieve other political goals (Jasanoff 1990). Many federal agencies, particularly regulatory agencies but also evaluative ones, use standing advisory committees, ad hoc panels, and other peer review mechanisms to evaluate their programs, in-house research, the scientific literature, and regulatory proposals (Smith 1992; Jasanoff 1990).

Recent efforts by Congress have sought to expand the domain of peer review in some ways. Bills introduced in the 106th Congress include: S. 746, to peer review cost-benefit and risk analyses of major rules, among other purposes; H.R. 574, to peer review regulations supported by scientific data; and H.R. 2639, to peer review the data used in standards promulgated by the Occupational Safety and Health Administration.[1] But even in such agencies as the Environmental Protection Agency, where peer review has become relatively well established (EPA 1998; 1997; 1992), questions remains about the appropriate use of scientific knowledge and how peer review can enhance (or retard) the regulatory process (Powell 1999).

This paper provides an introduction and overview to the use of regulatory peer review in the United States and a preliminary assessment of the proposed legislation that would further establish regulatory peer review. It is an early portion of a two-pronged research agenda that seeks to elaborate both the logical structure and the detailed procedures of regulatory peer review and other aspects of the use of scientific expertise in the policy process.

In elaborating the logical structure of regulatory peer review, the project builds on previous work on the logical structure of science policy. Following the traditional distinction in the science policy literature between "policy for science" and "science in policy" (Brooks 1968), this earlier work applies a principal-agent perspective to focus exclusively on the delegation inherent in funding research (Braun 1993; Guston 1996; van der Meulen 1998; Caswill 1998). Applying the same principal-agent perspective to "science in policy," the agenda seeks to articulate a more sophisticated analytical framework for peer review (and other uses of expertise) that both scholars in several disciplines and practitioners in advice-producing and -consuming arenas can appreciate (Guston in preparation).

[1] The US Supreme Court, in its *Daubert v. Merrell Dow*, *GE v. Joiner*, and *Kumho v. Carmichael* decisions, has likewise sought to expand the purview of peer review as one measure of the admissability of expert testimony in the courtroom.

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In elaborating the detailed procedures of regulatory peer review, the project extends an approach to studying science and scientists by following them out of the laboratory (Latour 1987) and into arenas in which they are called upon to come to judgments in a more public and accountable way. It also extends an approach to studying science and scientists that emphasizes observing how, through their rhetoric as well as the establishment of policies and procedures, they attempt to demarcate their vision of scientific from non-scientific activities (Gieryn 1995; Jasanoff 1990). Such detailed scrutiny, for example, can yield a more complete, scholarly understanding of consensus and consensus formation in regulatory science, as well as create some precise, policy-relevant knowledge about the decision making of expert advisory committees (Guston 1999). Ultimately, the project will synthesize both perspectives in a way that has been done for "policy for science" (Guston 2000).

This paper provides some preliminary descriptive work for the agenda. It begins by attempting to define peer review and making two sets of analytical distinctions -- the first among among four different procedural aspects of peer review (in order to set the stage for detailed procedural research) and the second among three different types of peer review (in order to clearly identify the category of regulatory peer review). The next section reviews the literature that deals with regulatory peer review in particular. Next, the paper presents some brief case studies of how agencies already use peer review in regulatory and evaluative missions. Finally, the paper assesses whether the legislation the 106th Congress has been considering is worthwhile and what additional research is necessary on regulatory peer review.

Analytical Distinctions: Definitions, Aspects, and Types of Peer Review

Defining Peer Review

Traditional accounts locate the origins of peer review in the 17th century Royal Society, which implemented a practice of distributing manuscripts to its members for commentary and advice prior to publication in the Society's *Philosophical Transactions*.[2] Former chemist and science policy scholar Arie Rip (1985:84) notes that "the Jesuit astronomers of the Collegium Romanum, who critically evaluated Galileo's claims, and the mathematicians who advised about the imprimatur of his books" could just as easily be cited as the original peer reviewers, but such an identification would be contrary to other scientific myths.

Rip's point is that locating a particular origin of peer review is, in part, presuming to define its role in the scientific community in a particular and potentially uncritical way. While his point is well-taken, for the purposes of this paper the perspective of peer review developed by the General Accounting Office (GAO 1999) in its survey of federal practices seems sufficient: peer review is the process of reviewing of scientific or technical merit by competent persons with no unresolved conflicts of interest. GAO arrived at this definition empirically, through a survey of all federal research and

[2] Zuckerman and Merton (1971) focus on the *Transactions* in their study of the institutionalization of JPR; Kronick (1985:24) identifies a number of antecedent practices, however.

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development (R&D) funding agencies. Key to the definition's usefulness, however, is further defining what constitutes scientific or technical merit, who the competent persons are and how they are selected, what conflicts of interest need to be resolved in what ways, and how the process of review relates to outcomes.

Aspects of Peer Review

In order to contextualize peer review beyond the ability of a definition like GAO's to do so, the paper examines peer review practices along four dimensions critical to its performance and management:

1. **Jurisdiction**: What scope of scientific propositions or products are subject to review, who decides, and how? (This aspect relates to the constitution of scientific or technical merit.)
2. **Format**: What is the format of the peer review? Does it use panels or individual reviewers? Are they masked reviews? What is the relationship between the peer reports and the decision made? (This aspect relates to the influence of process on outcome.)
3. **Instructions**: What are the instructions given to reviewers? Do they specify certain criteria for particular consideration? (This aspect relates to both merit and process.)
4. **Participation**: What rules govern participation in peer review? With what kind of discretion and under what restrictions do reviewers participate? (This aspect relates to both competent persons and conflicts of interest.)

Clearly, the content of the dimensions of jurisdiction, format, instructions, and participation will vary over journal, funding, and regulatory peer review. Part of the purpose of the paper will be to elaborate the similarities and differences in this way.

Types of Peer Review

This paper addresses three primary types of peer review: funding peer review, journal peer review, and regulatory peer review.[3] Institutionally and, often, procedurally distinct, these three types of peer review share a roughly similar timing in their breadth of influence in the American polity. Although there had been isolated episodes of review early in the history of the Republic's scientific institutions, peer review as a system did not become institutionalized generally until the middle of the 20th Century.

In **funding peer review** (FPR), program managers (or other officials) seek the opinions of experts about the worthiness of research proposals for financial support. Among the earliest examples of funding peer review are: the Smithsonian Institution, one of the nation's oldest public scientific organizations, which created an advisory committee for

[3] It does not address other aspects of peer review, including: the evaluation of academic personnel for promotion and tenure; the selection of individuals for membership in honorific societies and other awards; the professional reviewing of patient records in hospitals (Garfield 1988a); and the evaluation of classroom teachers by other teachers.

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reviewing and recommending funding proposals in the 1840s; the Navy Consulting Board, chaired by Thomas Edison, which in 1915 began reviewing requests for funding from inventors (Savage 1999); andthe Hygienic Laboratory, the predecessor to the National Institutes of Health (NIH), which pioneered peer review in 1902 with a congressionally mandated advisory committee (Smith 1990). The National Cancer Act of 1937, and later the Public Health Service Act of 1944, legitimated the awarding of grants through an advisory council to researchers in universities and other institutions, and with NIH's creation of its Division of Research Grants and the original review groups, it established its nascent peer review system (Smith 1990).[4] At the National Science Foundation (NSF), however, FPR was only implicit at the start. An early guide to NSF's programs left the process of evaluating proposals unaddressed, although NSF's governing body, the National Science Board (NSB), understood that after staff evaluated proposals, they would send them to advisory bodies before presenting them to NSB for statutory approval (England 1982).[5] Other programs, such as the Office of Naval Research and the Defense Advanced Research Projects Agency, granted greater discretion to government personnel.[6] The decision to rely on managers at defense agencies was linked to the decision to rely on contracts rather than grants as a mechanism of funding (Sapolsky 1990).[7] In the federal government, the strong manager alternative has generally thrived only in defense areas, where research has more explicit, consensual programmatic goals.[8] Strong managers also thrive in private foundations that give research grants. Beginning in fiscal year 1996, the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) "have jointly provided annual direction to agencies encouraging them to emphasize the funding of peer-reviewed research over non-peer-reviewed research" (GAO 1999:4). Neither OSTP nor OMB provide agencies with concrete guidance on how to perform peer review, however.[9]

In **journal peer review** (JPR), the editors of professional journals seek the opinions of experts about the worthiness of manuscripts for publication. An early example of peer review for publication occurred when President Thomas Jefferson, who commissioned the Lewis and Clark expedition, requested the American Philosophical Society to review

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[4] Sapolsky (1990:95n29) suggests that NIH found a model for peer review in the Rockefeller Fund, which began the practice in 1930 (but Rockefeller's reasons for doing so are obscure). Sapolsky adds that NIH originally had a two-tiered process including academic scientists in one tier and government scientists in the other, but the role of the latter diminished as the former objected.

[5] William E. Benson, assistant to the director of NSF's Earth Sciences program in the 1950s, distinguished between the various meanings of peer review, opining "that NIH peer review is not just peer judgment but almost peer decision..., whereas here in NSF the system is peer advice" (England 1982:358). By this, Benson meant that program officers at NSF had greater discretion over awards than counterparts at NIH. OTA (1991:127) suggests that manager discretion has become more explicit at both NSF and NIH.

[6] At ONR, however, managers might make informal inquiries of colleagues (Smith 1990; Sapolsky 1990).

[7] In this choice, however, ONR ignored the use of the National Academy as a reviewer for Army and Air Force projects (Sapolsky 1990:94-95).

[8] Manager discretion may have some advantages over peer review, including its ability to gauge project relevance, implement programmatic changes more rapidly, and fund proposals that may be counter to prevailing fashion (OTA 1991:126). Some scientists speculated, however, that ONR managers favored their alma maters and supported prominent scientists simply for the prestige of their portfolios (Sapolsky 1990:96).

[9] OSTP has given guidance to agencies about the use of peer review for the purpose of program evaluation under the Government Performance and Results Act of 1993. See NSTC (1996).

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the expedition's report prior to its publication (Savage 1999:5). Although some professional journals may have used informal varieties of peer review, JPR did not become widespread among scientific journals until the mid-20th century, in part propelled by the increasing specialization of modern science (Chubin and Hackett 1990). It was not until the mid-1960s that major journals began publishing information about their peer review processes (Hargens, in CBE 1991). By that time, JPR was widespread but not universal: Zuckerman and Merton (1971) cite a 1968 study that found 71% of 156 journals in 13 countries made some use of peer review, including 47 of 49 journals in the United States. More recently, Locke (1985) reports that more than three-quarters of scientific journals in the West use peer review, and that editorial review in China and the Soviet Union was not dissimilar.

In **regulatory peer review** (RPR), a slightly more diffuse category, in which government officials seek the opinions of experts about the quality of scientific and technical inputs to regulatory or other policy decisions. Also in mid-century, federal agencies began to establish a peer review system by appointing scientific advisory committees to keep themselves abreast of technical advances, oversee their scientific programs, and legitimate their policy decisions (Jasanoff 1990; Smith 1992). More than any other Western democracy, the United States makes use of outside experts to advise its governing institutions (Weiss 1992), and the use of ad hoc advisory committees dates back to the early days of the Republic (Smith 1992).[10] During the Civil War, Congress created the National Academy of Sciences, not only as an honorific institution, but also to "investigate, examine, experiment, and report on any subject of science" when called upon by government (NAS 1985).[11] NAS created the National Research Council (NRC), its operating arm, in 1916, which in 1918 was perpetuated by a request from President Wilson. War again sparked a turn to technical advice, with the formation of the National Advisory Committee on Aeronautics in 1918.

The real proliferation of advisory committees, both technical and otherwise, occurred with the management of the twin crises of the Depression and World War II. The Depression-era Science Advisory Board, for example, failed in its attempt to bring scientific thinking and technological applications to bear on the social problems of the 1930s (Hart 1998:72-75). A chain of advisory boards relating to defense science, culminating in the creation of the Defense Science Board in 1956, has been an example of the "successful use of science advisers" (Smith 1992:48-67),[12] and the defense model

[10] While this greater use of outside experts is patently true for the executive branch of government, it may be less true for the legislative branch. See Bryner (1992) for a pessimistic vision of Congress's use of policy analysis. See Vig and Paschen (1990) for a review of relatively robust parliamentary offices of technology assessment in Europe in the years since the demise of the U.S. congressional Office of Technology Assessment. See Bimber (1996) for OTA's history.

[11] The National Academy complex evolved over time with continuing federal involvement. The National Academy of Engineering and the Institute of Medicine were established under the NAS charter in 1964 and 1970, respectively. See NAS (1985).

[12] For insight into the early politics of this chain, see Blanpied (1995).

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was very influential in the creation of the President's Science Advisory Committee later in the second Eisenhower administration.[13]

The 1973 creation of EPA's Science Advisory Board formally brought the advisory committee model to regulatory science (Jasanoff 1990; Smith 1992). Other agencies appointed advisory committees and increased their use of professional and honorific societies, including the National Academy of Sciences and others, for similar purposes. Because of the diversity of policies and problems that emerged at many agencies, the National Research Council (1983) recommended the heuristic separation (but not the radical institutional separation) of risk assessment and risk management in risk policy. With the assistance of OSTP, EPA implemented these changes and withstood additional external challenges (Jasanoff 1990).

The proliferation of advisory committees in the twenty-five years after the war led Congress to pass the Federal Advisory Committee Act (FACA) in 1972, setting down rules governing their use and mandating some degree of openness in their activities and balance in their membership.[14] The General Services Administration (GSA), which is charged by the President to fulfill FACA's reporting requirements, estimates the number of FACA committees at just under 1000, a number that has been quite steady and a modest reduction in line with President Clinton's 1993 Executive Order 12838 (GSA 1997). In fiscal year 1998, GSA counted 23% of FACA committees as scientific/technical and another 14% as grant review (GSA 1999), percentages consistent with previous years. In 1997, a Federal court ruled that the government "utilized" the National Academy complex under FACA and since, with some legislative direction (cite law), the Academy has altered its procedures to provide greater openness (GAO 1998).

In recent years, particularly since the 104th Congress, ideas about regulatory reform, tort reform, and other issues in the application of science to decision making have included a role for regulatory peer review.

Peer Review in the Regulatory Environment

There is no coherent literature on RPR and only a few major works of scholarship and/or analysis that bear directly on the topic. Earlier work, such as Ashford (1984), is still very much in the tradition of participants in the process offering observations on and, perhaps, analytical frames for their experiences. Perhaps the most significant, broad scholarly treatment of RPR is Jasanoff (1990), although Smith (1992) is an important and relevant work as well. Other works deal more generally with science and risk in the regulatory

[13] PSAC persisted through the second Nixon administration, when President Nixon disbanded it. Congress reconstituted a presidential science apparatus in 1976, however, but it excluded an advisory council like PSAC. A White House Science Council was created in the Reagan administration, and a new President's Council of Advisers on Science and Technology was created in the Bush administration and endures through the Clinton administration. See Golden (1988) for various short takes on presidential science advising.

[14] Smith (1992:24) describes how the congressional impetus for FACA was driven by a perceived abuse of secret deliberations by advisory committees in USDA and EPA in their consideration of 2,4,5-T (dioxin).

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process (Graham and Weiner 1995; Carnegie Commission 1993a; Breyer 1993; Graham, Green, and Roberts 1988). There are also some studies that bear on RPR at particular agencies, notably Powell's (1999) recent study of the use of science at EPA (a discussion of which is deferred to the section on EPA). Together, the literature presents a patchwork perspective that suggests that the use of science in regulatory decision making has improved over time but still could use additional refinement, particularly with regard to its FACA responsibilities.

Ashford (1984) compares and contrasts the experience with science advisory committees at EPA and OSHA, two agencies he had the opportunity to serve. He focuses mostly on the intended functions of these advisory committees, making some helpful observations and introducing some useful analytical categories along the way. For example, he distinguishes among permanent (statutory), quasi-permanent (standing but administratively created), and ad hoc committees. He then claims that ad hoc-ness at OSHA led to an uneven approach to standard-setting, and that EPA's technique of drawing ad hoc committees from its SAB membership permits both the flexibility that ad hoc-ness seeks and the continuity that OSHA does not achieve.

Ashford also places the burden of performance significantly on the FACA-mandated balance of advisory committees, suggesting that FACA's language and legislative history seek balance in order to: increase the role of those affected by decisions in advising; avoid over-representation of any particular geography, interest, or discipline; include consumers and public interest representatives; include informed laypersons; and prevent dominance of any private interests from making special claims on decision makers. He summarizes these in three dimensions of balance: competence, discipline, and allegiance. The scientific community -- which (through the voices of NAS and AAAS) supported President Reagan's veto of an explicit balancing law even in the wake of his SAB "hit list" -- may be a barrier to balance because its "desire to maintain the illusion of neutrality of science and scientists...may, as a practical matter, prefer covert stacking to overt balancing" (Ashford 1984:79). Balance does not prevent misuse, but it may avoid misuse under the perception of fair use.

Jasanoff (1990) also does not study RPR directly. Rather, she is interested in the broader question of how the role of science in policy can be restrained, useful, legitimate, and relevant all at the same time. Jasanoff begins her analysis by identifying a pattern in technical decisions from 1975 to 1980 in which proposals to regulate potential hazards, based on studies or risk assessments performed in-house, were followed by challenges from external experts and resulted in the withdrawal of regulatory proposals and subsequent damage to the reputation of agencies. She concludes, with other observers, that these cases (including nitrites, 2,4,5-T, Love Canal, and occupational cancer) suggested the need for more complete peer review within agencies; but she also argues that the particular resolution of these cases did not resolve the larger question of who would be the final arbiter of the technical competence of assessments: the agency, the courts, or an independent scientific body.

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One response to these controversies sought to separate science from policy (either in separate institutions or, less radically, by establishing firmer barriers within the same institution). NAS ultimately rejected the institutional separation of risk assessment and risk management, for practical as well as intellectual reasons, instead advocating the strengthening of peer review as an alternative. But peer review, Jasanoff argues, is a system originally designed for use in the realm of research science, which she distinguishes -- by virtue of goals, methods, endpoints, and institutional context -- from regulatory science.[15] Also recognizing shortcomings in journal and funding peer review, including that peer review is not a fail-safe mechanism for determining integrity or quality and that it can open the window to questions of validity rather than necessarily resolve them, Jasanoff is skeptical about the ability of peer review alone to solve the problem of scientific inputs to regulatory decisions.

Jasanoff's case studies explore these questions of peer review and regulatory decision making:

- In her case on EPA's Science Advisory Board, she traces an evolution from politicization and confrontation in the early 1980s to a more cooperative relationship later in the decade, concluding that successful RPR by SAB is a complex result of the historical accident of a backlash to political mismanagement, the intentional strategy of interest representation, and the ability of SAB to seem aloof from policy decisions while subtlety blending policy and science.
- The case of EPA's Clean Air Scientific Advisory Committee also shows an evolution -- punctuated by congressional action to clarify CASAC's role -- from controversy to accommodation, although EPA and CASAC did continue to dispute such science policy questions as what constitutes an adverse health effect, who were appropriate test subjects, and what constituted an appropriate risk assessment methodology.
- EPA's Science Advisory Panel illustrates a more enduring adversarial relationship in the provision of advice for pesticide regulation, especially over science policy questions about the nature of animal models of carcinogenic risk, the relative importance of individual studies versus the entire body of evidence, and questions about possible bias toward industry.
- Jasanoff's cases of FDA's use of advisory committees show many of the same difficulties of science policy issues, the benefits of give-and-take between the agency and advisory committees, and the possibility that science advice might push an agency into an area contrary to settled legal interpretations.

Jasanoff concludes that the institutional representation of science is important to making good regulatory decisions, but that negotiated rather than adversarial procedures are superior. This institutionalized science in the form of peer review, however, needs to be balanced in its representation of multiple disciplines and interests and its familiarity with the particular challenges of regulatory (as opposed to research) science. Such review should occur early to prevent unsubstantiated progress, but advice should still leave room for discretion on the agency's part.

[15] Jasanoff (1995) also focuses on the distinctive category of regulatory science.

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Smith's (1992) treatment of advisory committees is somewhat less nuanced but more broadly structured than Jasanoff's; it pertains less to RPR as such and more to the general problem of technical advising of executive agencies. After reviewing the history of such committees from the early days of the Republic and dwelling in some detail on the governing arrangements that encouraged and regulated advisory committees -- particularly the Federal Advisory Committee Act, the Freedom of Information Act, and their antecedents -- Smith also presents a series of loosely comparative case studies:

- Smith's study of the Defense Science Board demonstrates the successful long-term development of a tightly integrated advisory board, one that can survive particular controversies (such as the Strategic Defense Initiative) and challenges (such as a narrow base in the defense industry), but that may not be able to withstand the epochal changes in the role of defense and defense industries after the Cold War.
- Smith's portrait of EPA's Science Advisory Board shows remarkable likeness to Jasanoff's, as he traces the evolution of SAB from its early and self-serving vision of the simple provision of science advice to its latter and more nuanced development of expertise in regulatory science (which Smith (1992:69) defines as "a unique mixture of expertise and policy relevance").
- DOE Advisory Boards and NASA's Advisory Council are much less successful than DSB or SAB, largely because they operate in a more fragmented policy arena where the agency lacks basic consensus around its mission and political support is missing from top levels of government. DOE's boards operate without any consensus on the government role in civilian energy development and production, and NASA's Advisory Council has performed mostly as a "support group" for an agency embattled by fiscal difficulties, the sequelae of the *Challenger* disaster, and rifts in the scientific community about the nature of space exploration.
- Science advice in the State Department is the least successful example, but perhaps still an instructive one, as it was not just that the State Department failed to commit serious resources and attention to science advice over time, but it neglected a standing advisory committee largely because of the preference of officials for informal rather than formal technical advice.[16]
- Smith also survey's the history of science advice to the President, finding that the President needs science advice, but that the utility of that advice will depend almost entirely on the President, so the science advisor needs to perform like any other policy advisor and not like a scientist, per se.[17]

From these examples, Smith concludes that science advisory committees need: a clear mandate relating to an important problem (for the agency or the nation); an identifiable client to receive their advice; an active chairperson with, if possible, good personal relations with the client; and balance among outlook but congruence of purpose. Like Jasanoff, he finds that science advisors need to do more than science to be successful, not just for themselves but for the nation: "the democratic dialogue is not well served by

[16] The State Department has recently made some changes to improve its access to scientific and technical expertise.

[17] The Office of Science and Technology Policy, directed by the special assistant to the President for science and technology (the President's "science advisor") has, through the National Science and Technology Council, emphasized managing the R&D enterprise and de-emphasized expert advice.

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the simplistic notion that the advisory relationship is based just on objective information" (Smith 1992:65).

In 1993, the Carnegie Commission on Science, Technology, and Government released its report on *Risk and the Environment: Improving Regulatory Decision Making*. Although the "examination of environmental and risk-related policymaking focuses on the role of science" and "stress[es] the importance of sound science" (Carnegie Commission 1993a:117, 118) regulatory peer review does not loom large in the Commission's assessment. In its recommendations regarding "science, risk, and regulatory decision making," the Commission suggested that "[r]egulatory agencies should critically evaluate and take deliberative steps to improve their internal scientific capabilities and their means of integrating scientific and technological considerations into agency decision-making processes" (21). The Commission recommended that, to achieve this improvement, agencies should "seek advice from other government agencies" and appoint "[i]ndividuals with both public policy and scientific expertise...more frequently to senior positions" (21). Agencies should also "enhance their long-range planning capabilities by strengthening the linkages between research and regulatory policymaking efforts," including intramural research and planning and extramural research (22-23). Although the Commission acknowledged that "[e]xternal science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a wide range of issues [and in] serv[ing] as a bridge between government, industry, and academia," it also cautioned that "federal agencies should not rely so heavily on external advisory boards that internal scientific capabilities are neglected or are automatically assumed to be less credible than those undertaken by nongovernmental experts" (90-91).

Thus, peer review for regulations was not explicit in the Commission's approach to improving regulatory policy, but it was important in its approach to maintaining the quality of inputs to regulatory decisions. For example, the Commission promoted a comparative risk approach for regulation, and it argued that "[t]he *sine qua non* of relative risk analysis is scientific data" (82). It wrote,

> Utility and reliability are important criteria for inclusion of data in any inventory, and chief among the indicia of reliability of scientific data would mostly likely be favorable peer review. Data published in peer-reviewed journals would *a priori* be acceptable for incorporation. The agencies could also establish science advisory groups to help review potentially important but unpublished data....[But r]egulatory decisions often cannot wait until journal-quality science is available, and decision makers in such situations need access to any existing data that are not patently unreliable (85).

Short Cases in Peer Review: Regulatory Agencies

Many Federal agencies already practice forms of peer review for the science underlying their regulatory efforts. Other agencies with evaluative or assessment missions use

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advisory committees or similar forms of review as well. This section reports on the RPR practices of a number of these agencies, in an agency-by-agency format. It begins with regulatory agencies (EPA, FDA, and OSHA), continues with other evaluative agencies (NTP, OMAR, NMFS,...) and the National Academy complex, and concludes with RPR activities in states. An assessment of RPR according the previously detailed categories of jurisdiction, format, instructions, and participation occurs in the synthesis and discussion section.

Environmental Protection Agency

EPA is an independent agency charged with regulating the quality of the environment under a variety of laws protecting air, water, and soil and other legislative mandates. Because of its politically vulnerable position at the intersection of vital political and economic interests and uncertain science, EPA has developed perhaps the most elaborate structures, policies, and procedures for RPR. This short case focuses on developments since Jasanoff (1990) and Smith (1992) examined EPA.

Beginning in the early 1990s, EPA has focused extensive attention on its use of science in its own decision making. *Safeguarding the Future: Credible Science, Credible Decisions* (EPA 1992) -- itself a product of a peer advisory panel -- emphasized the importance of external peer review for EPA scientific and technical products, contact between EPA and external scientists, and the use of the best science in EPA decisions. Implementation of this agenda has taken some time, in part because of difficulties in developing standard operating procedures among various EPA divisions (Browner 1994). To this end, Administrator Browner created a Science Policy Council to "expand and improve peer review in all EPA offices." One of SPC's early products was "Guidance for Conducting External Peer Review of Environmental Regulatory Models" (Sussman 1994).[18]

A 1997 memo outlined the new policy for "peer review and peer involvement" in EPA (1997).[19] The memo described peer review as a "particularly important type of peer involvement" that "not only enriches the quality of work products but also adds a degree of credibility that cannot be achieved in any other way. Further, peer review early in the development of work products in some cases may conserve future resources by steering the development along the most efficacious course." The policy articulated that "major work products that are primarily scientific and technical in nature and may contribute to the basis for policy or regulatory decisions" normally should be peer-reviewed. Although the memo maintained that the policy "does not establish or affect legal rights or obligations," that "[m]inor variations in its application...are not a legitimate basis for delaying or complicating action," and that per review is not a formal part of nor a

[18] Powell (1999) reports that a 1994 Senate directive instructed EPA to seek help from NSF in the practice of peer review. Powell suggests, however, that NSF may not be a good model because it can afford a sole emphasis on proposal quality; whereas, EPA must consider relevance and multi-disciplinary problem orientation.

[19] A more complete chronology exists in Powell (1999), which also describes a 1996 GAO report that found uneven progress on implementing peer review and an internal study conducted by EPA's Office of Research and Development that reported few deviations from peer review requirements except in the area of models.

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substitute for rulemaking, the memo does recommend that the remarks of peer reviewers should be part of a decision record if the relevant work products have been reviewed. The memo also emphasized the need for careful management of a peer review process that could be "time-consuming and expensive" and is sensitive to issues of credibility should conflicts of interest occur.

Shortly thereafter, the Peer Review Advisory Group, a subcommittee of the SPC, published the Peer Review Handbook (EPA 1998). The *Handbook* serves as a guide for EPA staff and managers on the "organization and conduct of peer review." It recognizes a diversity of peer reviews "depending on the nature of the work product, relevant statutory requirements, and office-specific policies and practices (p. 9) and states that the determination of rules as "major" and therefore appropriate for peer review "will largely be case-by-case" and require the judgment of an assistant administrator, regional administrator, or their designee (p. 26). Criteria for peer review status include work products that: establish a significant precedent, model, or methodology; address controversial or emergent issues; have cross- or inter-agency implications; are costly; apply innovative approaches to problems, processes, or methodologies; and satisfy statutory or other legal mandate for peer review. The *Handbook* also exempts from review "scientific and/or technical methodologies or information [that] are commonly accepted in the field of expertise," although such exemption still would require documentation of acceptance in the field (p. 30). It appears that EPA does not regularly review cost-benefit analysis, and the agency may understand CBA as being such a commonly accepted method as not requiring review.

A Peer Review Leader (PRL) manages the review, and a Peer Review Coordinator oversees it. The PRL is supposed to create a formal record of each review and its outcome, sufficient for "an uninvolved person to understand what actually happened and why" (p. 37). The *Handbook* accepts the use of internal peer reviewers in some circumstances, provided that they are not employed in the same unit that produced the work. It also describes a variety of other acceptable peer reviews, including ad hoc and standing committees and workshops, and it suggests that when an ad hoc review occurs, more than one reviewer is usually necessary, although two or three may be acceptable. The *Handbook* recommends that informal review of the composition of reviewers may be helpful and that experts' positions should be balanced along the continuum of "technically legitimate points of view" but not be "too far to either extreme" (p. 47). The PRL formulates the charge to these reviewers, and the *Handbook* encourages attention to the charge by stating that, "[a]s a general rule, the time drafting a good charge letter is well-spent and is necessary for an effective peer review" (p. 43). Such review is supposed to occur prior to public comment.

The *Handbook* recognizes a relatively wide definition of conflict of interest (or perceived conflict of interest) as "when a person is affected by his/her private interests, or when he/she or his/her associates would derive benefit from incorporation of their point of view in an Agency product" (p. 47). It points to established forms and mechanisms for managing conflicts or potential conflicts at standing advisory committees. The *Handbook* acknowledges that interested experts may be among the most knowledgeable

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and allows for their participation under the conditions of disclosure of (potential) conflicts and balance among the reviewers (although in some conditions, e.g., for a potential reviewer with "a client or employer with a direct financial stake in the matter" (p. 48), the conflict will be "so direct and substantial" as to disqualify the expert). The *Handbook* equivocates on the applicability of the Federal Advisory Committee Act to peer review, suggesting that in some cases review by individuals (rather than consensus committees) or by committees of contractors may not be constrained by FACA.

Food and Drug Administration

FDA is an agency of the Public Health Service, and its mission is to ensure the safety of processed foods and the safety and efficacy of drugs and medical devices, among other related products.

Central to its function of approving new drugs and devices is FDA's review of the data submitted along with new drug applications (NDAs), and the principal activity of the advisory committees at FDA's Center for Drug Evaluation and Research is to make sure that these NDAs comply with statutory requirements for "substantial evidence" "consisting of adequate and well-controlled investigations." CDER makes use of these committees "so that final agency decisions will have the benefit of wider national expert input. Committee recommendations are not binding on CDER, but the agency considers them carefully when deciding drug issues."[20] Jasanoff (1990:154) reports that, as of 1986, FDA had "thirty-nine standing committees and panels associated with the Commissioner's Office, the National Center for Toxicological Research, and the Centers for Drugs and Biologics, Devices and Radiological Health, and Veterinary Medicine."[21] In stark contrast to the practice of journal editors and reviewers, however, FDA does not assume that the clinical inquiries described in the NDA have occurred. Rather, FDA engages in both random and for-cause audits of the clinical research unpinning NDAs (Nightengale and Kimbrough 1989).

CDER also takes advantage of non-FACA committees, for example, the Statistical Policy Coordinating Committee, which develops policies pertaining to the design and evaluation of industry studies and reviews CDER programs, staff, and publications with the goals of maintaining good statistical practice and creating a consistent approach to statistical analysis (FDA 1998). There is also a Biopharmaceutics Coordinating Committee, a Chemistry, Manufacturing, and Controls Coordinating Committee, and a Pharmacology/Toxicology Coordinating Committee, as well as several management coordinating committees for projects and information technology. The Carcinogenicity Assessment Committee is yet another internal committee responsible for providing CDER with additional review of carcinogenicity studies and support for other issues in carcinogenicity.

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[20] See http://www.fda.gov/cder/handbook/index.htm

[21] Jasanoff (1990) reports that many of these panels had been appointed by the FDA commissioner or division, but then the Department-level began exercising more control over appointments -- not necessary a salutary development as physicians were not above politicking for appointments.

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FDA has incorporated peer review as an important part of its centers' missions, as expressed in strategic planning documents. For example, the National Center for Toxicological Research conducts fundamental and applied research on the mechanisms of toxicity, providing analytical skills and experience that supports the agency's regulatory function.[22] It maintains a Science Advisory Board, composed of scientists from industry, academia, and consumer groups, and supplemented by topic-area experts from all sectors that FDA regulates. NCTR relies on SAB to review its programs. Studies conducted by NCTR researchers are verified by internal and external peer reviews, and NCTR encourages researchers to publish in peer-reviewed journals.[23]

FDA also uses peer review as an indicator or criterion for inputs into some decision making. For example, the agency recently issued a final rule on the dissemination by manufacturers of information about off-label uses for drugs, devices and biologics (FDA 1998:64555), requiring that any such information disseminated "must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication."

Occupational Safety and Health Administration

OSHA is an agency of the Department of Labor. OSHA has two primary mechanisms for receiving external advice: statutory advisory committees and ad hoc committees.

The Occupational Safety and Health Act of 1970 instituted a National Advisory Council on Occupational Safety and Health (NACOSH). Its purpose is to "advise, consult with and make recommendations" the Secretaries of Labor and Health "on matters relating to the Administration of the Act." The Council has a corporate membership, with two members each representing management, labor, occupational health professions, and occupational safety professions, and four represent the public. All are "selected upon the basis of their experience and competence in the field of occupational safety and health." Members serve two-year terms, and the Council holds between two and five meetings per year. The Council provides advice and recommendations upon the approval of a majority of its members, and all concurring or dissenting opinions (as well as abstentions and absences) must be recorded; individual members may also submit their own views on matters considered by the Council. The Council can also request the assistance of experts who can, at its discretion, participate in its deliberations. The Council also adheres to the rules of federal advisory committees.

The Contract Work Hours and Safety Standards Act also created an Advisory Committee on Construction Safety and Health. The Assistant Secretary seeks the advice of the Committee by presenting it with a proposal, as well as "any pertinent factual information available...including the results of research, demonstrations, and experiments." Such advice must be sought in the formulation of a rule to promulgate, modify, or revoke a construction standard under the Act. The Council must submit its recommendations by the date the Assistant Secretary has designated, which must be no longer than 270 days from the initial consultation. The Council's recommendations are advisory to the

[22] See http://www.fda.gov/ope/FY00plan/NCTR00.htm and http://www.fda.gov/ope/fy01plan/nctr01.html.
[23] In internal review, for example, statistical protocols are reviewed by members of the Biometry Staff.

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Assistant Secretary and the Secretary, and take place prior to the *Federal Register* process.

The Occupational Safety and Health Act also allows the Assistant Secretary to appoint an ad hoc advisory committees, composed of no more than fifteen "persons qualified by experience and affiliation to present the viewpoint of the employers involved" and "persons similarly qualified to present the viewpoint of the workers involved" (Ashford 1984: 74).

Ashford (1984: 75) asserts that NACOSH has been "a major forum for discussing and clarifying controversial issues before unnecessary adversarial interactions occur," including such episodes as cancer policy, reproductive hazards, the science-law interface, and internal research needs and opportunities. He also points out that the ad hoc committees have been less central to OSHA standard-setting, and indeed that they have been appointed less often than not. There are cases of OSHA following the advice of ad hoc committees, e.g., coke oven emissions standards, and cases of it ignoring advice, e.g., pesticide exposures. Ashford (1984:75-76) points to the transitory nature of such committees as an important element to their lack of success, although the flexibility of ad hoc committees for particular regulatory tasks may be desirable.

Short Cases in Peer Review: Evaluative and Assessment Agencies

Worth distinguishing because regulatory agencies bear burdens (APA) that these do not.

National Toxicology Program[24]

The National Toxicology Program (NTP) is an agency of the Department of Health and Human Services (DHHS), created in 1978 with the mission "to evaluate agents of public health concern by developing and applying the tools of modern toxicology and molecular biology" (NTP 1999, 2). NTP is a collaboration among the National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH), the National Institute for Occupational Health and Safety of the Centers for Disease Control and Prevention (NIOSH/CDC), and the National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA).

NTP uses a Board of Scientific Counselors (BSC) to provide peer review for a number of agency activities. The full BSC provides oversight for the Center for the Evaluation of Risks to Human Reproduction. The Center organizes ad hoc Scientific Review Panels, which review background documents and evaluate two or three chemical each year for evidence of their possible adverse effects on fertility and childbearing; the resulting reports are published in *Environmental Health Perspectives*. The Scientific Review Panel draws its members from an Expert Registry comprised of scientists nominated by the public.

[24] Most information in this section drawn from NTP (1999).

PM3001241788

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The BSC's Technical Reports Review Subcommittee reviews toxicological studies of substances that have been nominated for study from a variety of sources and approved by a public process that includes review by both the full BSC and an internal Executive Committee. The BSC's Report on Carcinogens Subcommittee reviews the record on substances that have been nominated as "known" or "reasonably anticipated to be" human carcinogens in preparation for their possible listing in the biennial *Report on Carcinogens*.[25] NTP staff recommend potential members of BSC to the NTP director, based on the Board's needs for technical expertise and balance; the director nominates members, who are appointed by the Secretary, DHHS.

NTP also maintains a Center for the Evaluation of Alternative Toxicological Methods (NICEATM), which provides operational support to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), established in 1997 to "reduce, refine, or replace the use of animals in research and testing" (NTP 1999, 16). NTP's Advisory Committee on Alternative Toxicological Methods oversees the programs of NICEATM and ICCVAM and advises them on activities and priorities. The Advisory Committee is "composed of knowledgeable representatives from academia, industry, public interest and animal welfare organizations, other agencies, and the international community" (NTP 1999, 17), and its members are selected in much the same way as members of BSC. When ICCVAM evaluates a proposed alternative method, it convenes a peer review panel to develop "a scientific consensus on the usefulness, limitations, and validation status" (NTP 1999, 17), the conclusions of which are then forwarded to regulatory agencies for judgments according to their unique mandates.

Office of Medical Applications of Research (OMAR)

OMAR, part of the National Institutes of Health, runs consensus development conferences for the purpose of assessing and transferring new medical knowledge and technology to medical practitioners. Created to manage a controversy over breast cancer screening in 1977, consensus development conferences became the primary mechanism for technology transfer at NIH through the early 1980s (OTA 1982), and OMAR has disseminated more than 120 consensus and technology assessment statements produced through this process.[26]

Consensus statements are written by "broad-based, independent panels of non-Federal, nonadvocate individuals knowledgeable in the field of medical science under consideration."[27] Panels typically include medical researchers, providers,

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[25] Along with three other internal committees -- the RG1, RG2, and the Executive Committee, which are all composed of Federal employees from NTP and its participating agencies -- the Subcommittee votes on each substance nominated. Based on the votes of all the committees, the director of NTP makes recommendations to the Secretary, DHHS, who issues the *Report on Carcinogens* and its list of substances known and reasonably anticipated to be human carcinogens. Substances nominated for delisting are handled the same way.

[26] See http://odp.od.nih.gov/consensus/about/about.htm.

[27] Denmark altered the consensus conference format by replacing the expert panel with lay citizens. Such citizens' panels have become popular ways in Europe and elsewhere of conducting technology assessments and enhancing public understanding of science.

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methodologists, and a public representative; to avoid the appearance of conflict, panelists may not be Federal employees. Panels range in size from nine to sixteen, but average twelve or thirteen.

The panel hears testimony from experts and the public for one and one-half days and then convenes in executive session to draft the statement which, upon completion on the third day, is circulated among the broader audience for comment. Because the conference "is an exercise in peer review, in which the panel reviews information presented by the experts, panelists should not be speakers." The panel then revises the statement, which is later released (on WWW and in the lay press) and usually published in the professional medical literature. According to OMAR, the panel and any recommendations are not advisory to NIH and "[a] consensus statement is not a policy statement of NIH or the Federal Government."

Topics for consensus development conferences are generated from recommendations across government and the public.[28] After a topic is chosen, a conference takes nine months to one year to schedule plan, as a planning committee -- composed of government employees with particular expertise, who have been screened for conflicts -- meets to select panelists, presenters, and articulate the specific questions that structure the conference.

Some commentators (Markle and Chubin 1987; IOM 1990) have recommended that OMAR expand the purview of consensus development conferences beyond narrow technical considerations. To some extent, this expansion has occurred, but "the primary purpose of a CDC is to provide scientific evaluation. To this end, the statements in general and the recommendations issued in particular should focus on medical safety and efficacy, although they may refer to other issues [e.g., economic, sociologic, legal, and ethical] in passing."

National Marine Fisheries Service (NMFS, or NOAA Fisheries)

NMFS has a mandate to provide the "best science available" to regional councils and others who participate in developing fisheries management plans. Peer review, using both internal and external reviewers, is an important part of that process.

Two mechanisms of internal review are stock assessment workshops (SAWs) and stock assessment research committees (SARCs), which review stock assessments for fish species under management. Workshops and committees are conducted at regional science centers and deal with fish species in those regions. SAWs and SARCs vary in depth and duration -- as short as an afternoon or as long as a week -- depending on how much advance preparation is required. Staff scientists, who develop the stock assessments, attend the meetings. Occasionally, an external speaker may attend to discuss new developments. SAWs are open to the public.

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[28] Consensus development conferences synthesize new information, and thus they differ from the clinical guidelines offered by the Agency for Healthcare Research and Quality, which synthesize information about existing practice.

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The stock assessments derived from SAWs and SARCs are submitted to the relevant Regional Fishery Management Council for that species, along with recommendations for the development of the management plan. The council's Science and Statistical Committee then further reviews the stock assessment. SSCs are composed of biologists, statisticians, economists, and social scientists from academia and state natural resource agencies. SSCs do not have to accept the recommendations of NMFS scientists to develop the management plan. They may also question the conclusions of the stock assessment when making their recommendations to the council. NMFS may have stock assessments externally reviewed if there is a problem achieving the requisite consensus.

NMFS uses internal and external review for other science used for regulatory purposes. Regional councils submit data that may be used to designate ocean or coastal environments as Essential Fish Habitats. The underlying science, as well as science supporting any potential restoration of habitat, is reviewed externally and internally. All review is done in an open fashion by both panels and individuals, and instructions given to reviewers are specific to the product being reviewed. NMFS identifies external reviewers through institutions such as the National Research Council, professional organizations (e.g., American Fisheries Society), recommendations of other scientists, and academia.

The Northeast Regional SAW conducts peer review of stock assessments twice each year.[29] The SAW determines which species to assess and establishes the terms of reference for the assessment. Each SAW cycle begins and ends with the meeting of the SAW Steering Committee and includes: Working Group meetings, where analyses are prepared for review; a five-day SARC meeting, where analyses are peer-reviewed and advice for managers is developed; and a two-session Public Review Workshop. Participants in this process include: NMFS scientists and managers; representatives from state fishery agencies, regional fishery management councils and fishery agencies outside the region; academic and other non-governmental participants; and industry members.[30] The time frame for assessments is generally dependent on legislatively mandated deadlines.

NMFS has a Division of Research, Analysis and Coordination (ST2) within its Office of Science and Technology. ST2 is responsible for implementing NMFS's Strategic Plan for Fisheries Research, as well as for helping to ensure "the quality and credibility of NMFS fisheries science."[31] ST2 supports the NMFS's decisions on national standards for fisheries management. Among ST2' s major projects in science quality assurance are:

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[29] The SAW Steering Committee, composed of directors of NEFSC and NERO, the Mid-Atlantic Fishery Management Council [MAFMC], New England Fishery Management Council [NEFMC], and the Atlantic States Marine Fisheries Commission [ASMFC]), directs the process.

[30] The Sustainable Fisheries Act has also mandated NRC review of stock assessments for important species.

[31] See http://www.st.nmfs.gov/st2/reviews.html.

PM3001241791

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- NMFS Science Center Accreditation and Certification, which will use an independent panel of experts to set benchmarks for the quality and integrity of fisheries science data;
- Center of Independent Reviewers, which will create a pool of external experts whom the agency tap to review the stock assessments, new management methods, scientific programs, and grant proposals, and to participate in the design of those enterprises.[32]
- Methodological Peer Reviews, conducted in coordination with NMFS science centers, to produce reliable data for the regional fishery management plans, e.g., the Northeast Fisheries Science Center's Workshop (SAW--16) on the American lobster fishery.
- National Peer Reviews, mandated by the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the scope of which ranges from developing recommendations for applying ecosystem principles in fishery conservation to evaluating the research and management of red snapper in the Gulf of Mexico.
- NMFS Stock Assessment Improvement Plan, which will implement ten recommendations contained in a report, *Improving Fish Stock Assessments*, by the National Research Council's review of the current stock assessment methods and models.

National Academy of Sciences

Initially chartered by Congress in 1863, the National Academy of Sciences -- and the associated Institute of Medicine and the National Academy of Engineering -- is an honorific and an advice-giving body. The operating arm of the National Academy complex is the National Research Council. The Academy complex conducts studies from requests by Congress,[33] federal agencies, and foundations, and is subject to only partial public disclosures under the Federal Advisory Committee Act Amendments of 1997 (P.L. 105-153). In this role, the Academy complex serves a function akin to peer review for federal agencies, often evaluating programs, helping to set long-term research priorities, and providing other scientific and policy advice. The Academy complex identifies risk-related reports as "among the most difficult and potentially controversial" of its activities (NRC 1998).

Staff of the Academy complex choose members for its committees, with the advice of standing boards and commissions and the final approval of the chair of the NRC (who is also president of the NAS; NRC n.d.). The Academy complex recognizes that the "credibility of a report can be weakened if the committee that produced it is perceived to be biased" (NRC 1998:9), and to this end it requires committee members to complete a list of "potential sources of bias and conflict[s] of interest" and discuss it with their fellow members. Only on rare occasions are potential biases or conflicts publicly disclosed or do they serve to disqualify a potential member. The Academy complex calls for

[32] Congress recently appropriated funds for the compensation of external reviewers who participate in the Center of Independent Experts

[33] Congress does not appropriate directly to the Academy complex, however, but funds it through agencies. A small number of studies are self-initiated.

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committee members to "separate fact from opinion, analysis from advocacy" (NRC 1998:12), but nevertheless recognizes that in "studies involving incomplete or inconclusive data, the collective experience and reasoned judgment of committee members become crucial factors in developing conclusions and recommendations" (NRC 1998:13).

The Executive Committee of the NRC's Governing Board reviews and approves study proposals. All studies, as well as workshop proceedings and other documents, undergo "an independent review by anonymous experts who were not involved in the report's preparation" (NRC 1998:17). The Academy believes that this "independent, rigorous review is a hallmark that distinguishes the NRC/IOM from many other organizations offering scientific and technical advice on issues of national importance" (NRC 1997). The Report Review Committee, composed of about 30 members of NAS, NAE, or IOM, oversees the review, which is managed by the board or commission in charge of the study. RRC ensures that: "the report addresses the approved study charge and does not go beyond it; the findings are supported by the evidence and arguments presented; the exposition and organization are effective; and the tone of the report is impartial and sensitive policy issues are treated with appropriate care" (NRC 1998:18). Study committees have an opportunity (and are required) to respond in writing to report reviews. A monitor, appointed by RRC (and often a member of it), and/or a review coordinator, appointed by the commission or board, evaluates the responses to the review and defends the interests of the reviewers. NRC does not release reports until the monitor, the coordinator, the sponsoring board or commission, and the study panel are all satisfied. Names of principal reviewers are released after the report is published, but reviews themselves are single-blinded. This review by RRC is highly formalized and may include the services of 20 or more reviewers and produce a review record longer than the report itself.

States

There is no systematic information about the use of RPR in the states, although there is evidence of real interest among the states in the role of science in policy making (Andersen 2000; CGS 1999). According to a source at the National Conference of State Legislatures, a vast majority of states rely on US EPA for their scientific and technical analyses pertaining to environment.

One exception is California, where peer review is a robust part of the regulatory process. In 1997, Governor Pete Wilson signed SB 1320, which contained a peer review mandate.[34] Also in 1997, the Risk Assessment Advisory Committee issued a final report that asked for peer review to be applied more consistently throughout Cal/EPA. The 1998 Strategic Plan seeks to "[e]nhance the use of external peer review of scientific rules to ensure that the best science is used in all of Cal/EPA's environmental efforts," and that

[34] California's Proposition 65 also mandates a peer function: "A chemical is listed if the 'state's qualified experts'--an independent panel of scientists and health professionals appointed by the Governor--find that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm." See www.calepa.ca.gov/publications/factsheets/1997/prop65fs.htm.

PM3001241793

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year Cal/EPA (1998) published a "Policy and Guiding Principles for External Scientific Peer Review."

Parts of Cal/EPA use peer review for different regulatory purposes. The 1997 legislation specified external peer review for particular work products of Cal/EPA's several divisions. For example, the Air Resources Board must review its ambient air quality standards and its exposure assessments for toxic air contaminants (Cal/EPA 1997). ARB describes extensive opportunities for peer review in its pre-regulatory "Work Plan for Conducting an Airborne Environmental Fate and Transport Analysis of Ethanol-Containing Gasoline."[35] The Department of Pesticide Regulation sends draft risk assessments out for peer review (for 24 active pesticide ingredients in the year prior to mid-1999). Cal/EPA (1998:App.B) recommends a different type of peer review panel depending on the nature of the issue and the expected product. For example, it uses a Scientific Review Panel to review risk assessments for airborne toxics prior to rulemaking, but it uses the National Academy of Sciences for reviewing comprehensive risk assessments, e.g., of methyl bromide. SB 1320 requires review for "any rule, as defined, establishing a regulatory level, standard, or other requirement for the protection of public health or the environment," but Cal/EPA recommends consideration of reviews for many internal, preliminary, or other work products or analytical methods.

Cal/EPA (1998:4) views peer review as "an objective, critical review of a draft Agency scientific work product typically by independent scientific experts" that can occur at "several discrete points...[but] is typically characterized by a one-time interaction or a limited number of interactions...[and] can also occur during the early stages of a project or methods selection." It intends peer review to enhance and improve the agency's technical work, rather than to serve as mere legitimation for the agency. Cal/EPA distinguishes between formal and informal peer review, as the former can more easily "ensure the transparency of agency regulatory actions and enhance the credibility of agency decisions" (1998:4), and between peer review and public comment, as the former usually occurs prior to public comment and the latter is open to issues beyond the scientific purview (1998:5). Cal/EPA holds that peer reviewers should be independent, meaning that they should not have participated directly or indirectly in the development of the product being reviewed, and that they should not be employed by the agency (advisory committee members are not considered employees).

There are a few particular, and possibly even idiosyncratic, uses of peer review in support of policy or regulatory decision making in states:

- The Michigan Environmental Science Board -- established by Governor John Engler by executive order in 1992 -- is "an independent autonomous state agency established to provide sound scientific and technical advice to the Governor of Michigan and to state departments, as requested by the Governor, on matters affecting the protection and management of Michigan's environment and natural resources."[36] The Board answers referrals from the Governor, who asks specific questions. A subcommittee

[35] See www.calepa.ca.gov/programs/mtbe/outline/carb.ppt.
[36] See www.mesb.org.

PM3001241794

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of the Board, with guests added as needed for their expertise, then provide answers. Referrals may include the review of: environmental impact statements, proposed environmental standards for permits or operating licenses, the methodology for establishing permit or operating license conditions that contain environmental standards that have not been established by administrative rule, and staff actions on permits and licenses. The Board's meetings are open, but there is no formal public comment.

- North Carolina has a standing Scientific Advisory Board on Toxic Air Pollutants, composed of five scientists who review new or revised acceptable ambient level guidelines for air toxics and who conduct risk assessments. Meetings of SAB are open to the public "and participation by interested groups is not only allowed, but encouraged."[37] A broader Environmental Management Commission adds economic and feasibility concerns, and an Environmental Review Commission serves as gatekeeper to the legislative process.

Defining Peer Review

There is no authoritatively fixed definition of peer review in any arena -- funding, journal, or regulatory. Appendix I shows the diversity of definitions of FPR that federal funding agencies use. Nevertheless, GAO's observation that FPR across the government involves the review of scientific or technical merit by competent persons with no unresolved conflicts of interest seems to encompass the variety of practice -- not just for FPR but also for JPR and RPR -- as long as the purpose of the review is explicitly added.

Key to this definition' s utility, however, is further defining what constitutes the difficult concepts of "scientific or technical merit," "competent persons," and "no unresolved conflicts." Indeed, in seemingly all circumstances of FPR and JPR, yet alone RPR, scientific or technical merit is supplemented by some concern for mission or audience relevance, programmatic or editorial balance, economic benefits, and other less strictly scientific or technical concerns. Often, the practice of peer review defines "competent persons" as including criteria in addition to strictly technical considerations. Managers of review may actively seek reviews from an intentionally diversified group of peers; the striking exception is "serial review" in the physical sciences, where an editor may make a determination based on the advice of a single reviewer.

The treatment of conflicts, as well as what it means to resolve them, is similarly diverse. In some instances, e.g., medical journals, consulting, membership, and employment relationships in and of themselves are sufficient for disqualification from publishing certain types of articles. In other circumstances, financial relationships, once disclosed, are permissible. Some funding agencies consider not just financial but also professional relationships and affiliations as potentially disqualifying, although they often rely on the judgment of potential reviewers and program managers to resolve such conflicts.

Although peer review may be a social practice that is a *sine qua non* of contemporary science, there is no one formula or recipe for its practice apart from its specific contexts.

[37] See daq.state.nc.us//offices/technical/toxics/risk/.

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Lessons from Funding and Journal Peer Review

Nevertheless, there are likely some lessons from the practice of FPR and JPR that may be relevant for the practice of RPR. The diversity of practice, representing differing histories, disciplines, visions, and so forth itself suggests that a diversity of practice in RPR may be expected and, perhaps, appropriate.

Despite its diversity of practice, the **jurisdiction** of FPR and JPR is procedurally clear and encompassing, but subject to modest discretion. These characteristics could be goals for RPR.

The **format** of FPR and JPR is flexible within bounds, and decision makers retain a great deal of discretion in the face of peer advice. Agencies that use advisory committees for RPR are likely familiar with this flexibility and discretion, although public, legislative, and judicial scrutiny complicates the notion of agency discretion. Achieving the same balance of flexibility and regularity in RPR as JPR and FPR accomplish may be difficult because of the strong and diverse interests and the legalized nature of the regulatory process.

FPR and JPR may take in the upwards of eight months to complete, and the material being reviewed is, in such cases, usually limited to 20 or 25 pages in length and to a relatively narrow field of practice or set of techniques. RPR would likely encompass a scope of materials an order of magnitude larger and more diverse and interdisciplinary in character. Such scope usually does not pose problems for committees but could pose problems for individual, ad hoc reviewers.

Instructions given to funding and journal peer reviewers are general and include considerations, including those mentioned above like programmatic, administrative, or editorial criteria, beyond strictly scientific merit. EPA, at least, recognizes that charges to peer reviewers are critical. But RPR nevertheless seems to use similarly vague instructions -- thus conflicts between agencies and advisory committees over what constitutes substantial evidence or adverse health effects that the literature documents. Furthermore, to the extent that regulatory peer reviewers extend their evaluations beyond strictly scientific merit, the less such reviews serve agency goals for either quality validation or legitimacy. The legislative proposals for RPR give little guidance for how potential reviewers are to be instructed.

The **participation** in FPR and JPR is subject to great discretion by the program manager or editor, but substantive expertise and identifying and resolving conflicts of interest are critical. Program managers and editors are expected to exercise intellectual leadership, helping define what it means to be part of the field in which they are funding or publishing research. This leadership clearly influences the choice of reviewers and the treatment of reviews (and researchers' responses to them). Agency officials are expected to exercise some political discretion, based on values held by their elected principals and the public, and these political considerations will clearly influence the choice of

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reviewers and the treatment of reviews. It is not clear how much peer review -- if it remains advice and if outcomes are significantly dependent upon the choice of reviewers -- itself can manage to constrain discretion beyond some modest addition of quality.

Both FPR and JPR are well-institutionalized in the social sciences, but there are some differences between review in the social and natural sciences that suggest that there is less of a consensus among practitioners of the former about what constitutes high quality. This finding seems to carry conflicting lessons for RPR, as there is no reason from practice not to subject regulatory social science to review, but that the application of such review may be more likely to result in divergence of opinion (or pure legitimation) rather than refinement of opinion.

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Synthesis on Regulatory Peer Review

Regulatory and other evaluative and assessment agencies appear to have made significant strides over the last decade in reforming and improving the way that they incorporate science into decision making. Impetus for this improvement has come from concerns for sounds science, as well as from strategic planning efforts and, perhaps, from constituency building efforts. Examples include EPA's Science Policy Council and its *Peer Review Handbook*, FDA's incorporation of peer review goals and methods into its strategic planning, and the National Toxicology Program's creation of its Board of Scientific Counselors.

The **jurisdiction** of RPR is more variable and flexible than FPR and JPR, except in cases of legislative mandates or engaged agency effort. The jurisdictions of legislatively mandated advisory committees, for example, is relatively clear, as is the jurisdiction of their agency-created counterparts. But unless an agency undertakes the effort that EPA put into its *Handbook*, it is not clear that the appropriate variety of work products -- including models, analytical and statistical methods, and other agency research -- will be peer reviewed. It is not clear at EPA if a thorough evaluation of the implementation of peer review procedures has occurred.

Almost all peer review -- whether funding, journal, or regulatory -- is responsive in its jurisdiction; that is, it reviews what is brought to it, but it does not actively seek out material to review. FDA's auditing process is somewhat different, as it reviews the conditions for, and the production of, new drug and other data in a random and for-cause basis. Given controversies over the access to data that forms the basis of regulatory decisions, some commentators (Cohen and Hahn 1998) have called for a more active public role in assuring data integrity.

The **format** of RPR usually involves FACA committees, although there are a number of other models including government-only panels (which are often coordinating as much as review committees) and individual, ad hoc review. FACA committees are technically advisory, but decision makers ignore them at real hazard of public, congressional, or judicial scrutiny. Accounts of the work of FACA committees in RPR (e.g., Jasanoff 1990) suggest that a flexible and ongoing negotiation between the committee and the agency, begun early in the work product, will be most successful.

The **instructions** involved in RPR vary in details, especially because RPR is applied to a variety of work products. Committees performing RPR may or may not have specific guidelines for their analyses, and there can be conflicts between committees and agencies over details that could have been more clearly specified, e.g., how to determine an adverse health risk. In instances without clear instructions, agencies engaging in RPR allowing reviewers an enormous amount of discretion in coming to influential judgments. EPA's *Handbook* recognizes this difficulty in its emphasis on crafting a high-quality charge to reviewers -- as does the National Academy complex.

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Some RPR specifies that only peer reviewed and publicly available documents should be used as inputs to decision making (e.g., NTP's *Report on Carcinogens*); other RPR is less strict (e.g., FDA's new rule for off-label uses includes non-peer reviewed reference journals, and agencies with public meetings cannot help but hear material that was not peer reviewed, although they may disregard it). The Supreme Court's *Daubert* decision held that peer review should be important but not dispositive in a trial judge's decision to include expert testimony. Some agencies (again, NTP is a good example) also have clear instructions for the threshold of decision making, for example, the number and type of studies of a particular finding that lead to a judgment of "known human carcinogen." Although this research could not be detailed enough to investigate those kind of instructions for each agency (or for each committee within each agency), the literature suggests that such clarity is not common but that it may be crucial to outcomes.

Participation is largely governed by FACA for the formal advisory committees, and thus some form of disclosure of conflicts, balance of membership, and public openness is standard. Non-FACA committees are often narrowly technical or broadly inter-agency. Even advisory bodies exempt from FACA -- the National Academy complex and NAPA -- have at least some recognition of role of balance and public openness, although it is much less robust under these circumstances. EPA's *Handbook* suggests that the solicitation of individual as opposed to consensus opinion is not subject to FACA, and thus participation in RPR could be more easily at the discretion of agency managers, but EPA also provides for some oversight of RPR as well. EPA also attempts to distinguish between simple peer involvement and more dedicated peer review, and between public review (which is not based in expertise and happens toward the end of a process) and peer review (which is based in expertise and happens early in a process).

Synthesis Reviewing Proposed Legislation

There are several legislative alternatives represented by bills introduced in the 106th Congress promoting RPR; the major bill involves a comprehensive effort across all regulatory agencies, while other minor bills involve single agencies. Most comments will pertain to the major bill, S. 746. Appendix II contains relevant text from these bills, and Appendix III contains relevant excerpts from Senate Report 106-110, accompanying S. 746.

The proposals are generally clear about the **jurisdiction** of the RPR sought, which would be based on the estimated fiscal impact of the proposed regulation. This jurisdiction expresses an understanding that there are real costs to performing RPR, as EPA has acknowledged in its *Handbook*. The legislation would also assure that cost-benefit analyses (in effect, a social science input to regulatory decisions) would be peer reviewed as well. It would not address the wide variety of other work products, however. If it is the case, as Zuckerman and Merton (1971) speculate, that there is less consensus in the social sciences about what constitutes appropriate work, then it is possible that RPR of social science and economic analysis will not be convergent but will result in controversy and delay.

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The **format** for RPR described by the legislation would be flexible, allowing either committee or ad hoc review. There would be strict time limits on the review and agency officials would be required to respond to concerns raised by peer reviewers, although the precise relationship between the review, the response, and the details of the regulation at issue is not clear.[38] The review would occur prior to public notice. There is also some uncertainty about the nature of anonymity for ad hoc reviewers and the publicity of the reviews. The magnitude of the material submitted for RPR may be significantly greater than that submitted for FPR or JPR, and thus the time required to review it may be even longer than the variable but usually months-long process for grants and manuscripts.

The proposals are vague about what kind of **instructions** would be given to referees, of particular concern for ad hoc reviewers. Although the proposals specify a process for agencies to follow after RPR, it is somewhat formalistic and, like the Administrative Procedures Act and the process for incorporating public input, does not completely specify how significant negative or positive reviews should be for the agency's final decision making.

The proposals would exempt the described RPR from FACA, replacing it with **participation** from referees whom the legislation presumes could be unbiased (although the legislation anticipates that standing FACA committees could also be used, but not in FACA mode). Agencies would determine policies for conflicts. It is possible that agencies would use the legislation to end-run around existing FACA committees if such committees are viewed as roadblocks to regulatory proposals.

[38] This relationship may be something like that in the Administrative Procedures Act, which requires agencies to respond to public comments submitted in response to proposed rules, but does not require agencies to alter the proposed rules.

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